PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6: A61G 7/057, A47C 27/10

A1

(11) International Publication Number:

WO 00/24353

(43) International Publication Date:

4 May 2000 (04.05.00)

(21) International Application Number:

PCT/US99/25311

(22) International Filing Date:

28 October 1999 (28.10.99)

(30) Priority Data:

60/105,942

28 October 1998 (28.10.98)

US

(71) Applicant (for all designated States except US): HILL-ROM, INC. [US/US]; 1069 State Route 46 East, Batesville, IN 47006-9167 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): PRICE, James, H. [US/US]; 1524 Strathmore Lane, Mount Pleasant, SC 29464 (US). TAYLOR, Geoffrey, Locke [CA/CA]; 211 Oak Street, Winnipeg, Manitoba R3M 3P7 (CA). THOMAS, James, Milton, Cherry [US/US]; 1486 Greenshade Way, Mt. Pleasant, SC 29464 (US). STOLPMANN, James, R. [US/US]; 1011 Travers Drive, Charleston, SC 29412 (US), CALDWELL, Karl [US/US]; 102 Leighton Court, Summerville, SC 29485 (US). REPIK, Marla [US/US]; 14 Dunvegan Drive, Charleston, SC 29414 (US). BRIES, Nick [US/US]; 2546 Etiwan Avenue, Charleston, SC 29414 (US). MENSCHING, Kerry, J. [US/US]; 1406 Waterlilly Drive, Mt. Pleasant, SC 29464 (US).

(74) Agent: NIEDNAGEL, Timothy, E.; Bose McKinney & Evans LLP, 2700 First Indiana Plaza, 135 North Pennsylvania Street, Indianapolis, IN 46204 (US).

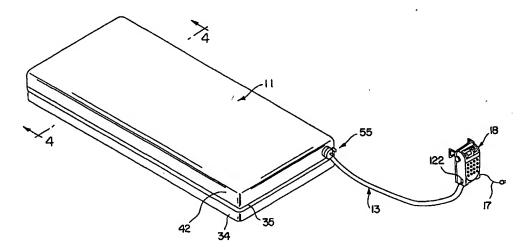
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: FORCE OPTIMIZATION SURFACE APPARATUS AND METHOD



(57) Abstract

A pressure optimization surface (10) is disclosed having a modifiable support surface (9) including a plurality of zones (46, 48, 50, 52) and an interface sensor (15) having a plurality of zones (96, 98, 100, 102) adjacent to and associated with the plurality of zones (46, 48, 50, 52) of modifiable support surface (9) and a controller (18). The sensor zones (96, 98, 100, 102) sense forces between the surface (9) and a patient (16) thereon and the controller (18) modifies the zones (46, 48, 50, 52) of surface (9) to reduce the force detected in each sensor zone (96, 98, 100, 102).

PCT/US99/25311

-1-

FORCE OPTIMIZATION SURFACE APPARATUS AND METHOD

Background and Summary of the Invention

5

10

15

20

25

30

The present invention relates to controllable surfaces, and particularly to surfaces for preventing and treating pressure ulcers.

Pressure ulcers in bedridden patients can be caused by excessive forces between the patient and a surface upon which the patient is resting. It is known to provide controllable mattresses that allow for adjusting pressures within a mattress surface. For example, it is known to adjust air pressure within multiple chambers of an air mattress, to reduce interface forces over a given bony protuberance based on sensed air pressures within the chambers.

According to the present invention, an interface sensing system eliminates the need to conduct independent interface force testing for a patient at each body and bed position on an ongoing basis. An intelligent control system is provided for adjusting internal cushion pressures in a mattress surface based on interface force measurements.

In the present invention, a method of minimizing a force between a modifiable support surface and a patient located thereon includes the steps of establishing an initial recorded force between the patient and the support surface, performing a first procedure including modifying the support surface in a first manner for a predetermined time increment, measuring the current force between the patient and the surface, comparing the current force to the recorded force, and replacing the recorded force with the current force. The first procedure is repeated so long as the current force is less than the recorded force, then a second procedure is performed including modifying the support surface in a second manner for a predetermined time increment, measuring the current force between the patient and the support surface, comparing the current force to the recorded force, and replacing the recorded force with the current force. The second procedure is repeated so long as the current force is less than the recorded force.

In the present invention, a support surface apparatus includes at least one support member for supporting a person, and a force sensor located on the at least one support member. The force sensor is configured to measure a force between the

10

15

20

25

30

person and the at least one support member. The apparatus also includes a mechanism configured to adjust a support characteristic of the at least one support member based upon the force detected by the force sensor to minimize the force between the person and the at least one support member.

In an illustrated embodiment of the present invention, a support surface apparatus includes at least one air bladder for supporting a person, a force sensor located on the at least one air bladder, an air supply coupled to the at least one air bladder, and a controller coupled to the force sensor. The force sensor is configured to measure a force between the person and the at least one air bladder. The controller is configured to adjust air pressure within the at least one air bladder based on the force detected by the force sensor to minimize the force between the person and the at least one bladder.

In addition, sensors contained within the force optimization surface of the present invention eliminate the need for individual equipment and monitors for measuring specific patient parameters such as heart rate, temperature, and respirations. An apnea monitor is provided to reduce and/or prevent occurrences of episodes of apnea. A built-in weight sensor system eliminates the need for external, cumbersome scales.

Additional features of the invention will become apparent to those skilled in the art upon consideration of the following detailed description of illustrated embodiments exemplifying the best mode of carrying out the invention as presently perceived.

Brief Description of the Drawings

The detailed description particularly refers to the accompanying figures in which:

Fig. 1 is a perspective view of a support surface system, lead/tubing assembly and control interface assembly according to the present invention;

Fig. 2 is a block diagram of a system according to the present invention including a controller, force, weight, heart rate, respiration, bladder pressure, and temperature sensors, the controller coupled to mattress control, display/print output, vital alert, and apnea oscillator systems;

10

15

20

30

Fig. 3 is an exploded view of the support surface system of Fig. 1 showing a bottom cover, foam support layer, air support layer, sensor layer, fire barrier, anti-sheer layer, and top cover;

Fig. 4 is a sectional view along line 4-4 of the support surface of Fig. 1;

Fig. 5 is a blowup of the cross section of the sensor layer enclosed in circle 5 in Fig. 4;

Fig. 6 is a flow diagram of the algorithm for a start phase controlling the inflation of the zones of the air support layer in accordance with the present invention;

Fig. 7 is a flow diagram of an upper level algorithm for a force management phase for controlling the inflation of the zones of the air support layer in accordance with the present invention;

Fig. 8 is a flow diagram of a lower level algorithm for a force management phase for controlling the inflation of the zones of the air support layer in accordance with the present invention;

Fig. 9 is a flow diagram of the algorithm for a max inflate mode for controlling the inflation of the zones of the air support layer in accordance with the present invention;

Fig. 10 is a front view of the controller of Fig. 1 showing various switches and indicators for monitoring and controlling force optimization surface; and Fig. 11 is a back view of the controller with back panel removed to show the valve assembly, compressor, and blower used in controlling the pressure in zones of the force optimization surface.

25 Detailed Description of the Drawings

Referring to Fig. 1, a force optimization surface 10 includes a support surface assembly 11, a control interface assembly or controller 18, and a lead/tubing assembly 13. Support surface assembly 11 includes a bottom cover 34, a modifiable support surface or modifiable support layer 9, a sensor layer 14, a fire barrier 38, an anti-sheer layer 40, and a top cover 42 as shown, for example in Figs. 3 and 4. In the illustrated embodiment modifiable support layer 9 includes a lower or foam/air support layer 36 and an upper or controllable air mattress layer 12. Air mattress 12 includes

20

25

30

one or more independently controllable air zones or chambers. An alternative support surface assembly 11 which can be modified by the addition of sensor layer 14 and fire barrier 38 as described herein for use as support surface assembly 11 in accordance with the present invention is described in U.S. Patent Application No. 09/281,888, filed on March 31, 1999, assigned to Hill-Rom, Inc., the assignee of the present invention, the disclosure of which is incorporated herein by this reference. While the illustrated embodiment increases and decreases pressure in air mattress 12 to modify modifiable support layer 9 in two different manners, it is within the teaching of the disclosure to provide mechanically or electrically modifiable support layers 9 made of foam, springs, or other suitable material which modify the firmness or surface configuration of the support layer in different manners to affect the force between the support surface 11 and a patient 16.

In the illustrated embodiment, air mattress 12 includes individual cylindrical cushions 44 divided into four independently controllable zones or groups referred to as head chamber 46, upper torso chamber 48, lower torso chamber 50 and foot chamber 52, two headers or plenums 54 per chamber, and four side bladders 56 per chamber (not shown in Fig. 3, only two of which are shown in Fig. 4). Each cushion 44 and plenum 54 is illustratively 4.0 inches (10.16 cm) in diameter 58. Each plenum 54 is fluidly coupled to each cylindrical cushion 44 in its associated chamber such as by opening 60 formed through end wall 62 of cylinder 44 and sidewall 64 of plenum 54 as shown, for example, in Fig. 4. Each plenum 54 is also coupled to an air supply 23 including a pump 31 and a blower 33 in controller 18 via mattress plumbing (not shown) coupled to lead/tubing assembly 13. Appropriate mattress plumbing is known and a specific embodiment applicable to the present invention is disclosed in U.S. Patent Application Serial No. 09/281,888. Each side bladder 56 is 1.5 inches (3.81 cm) in diameter 66. Illustratively each cushion 44, plenum 54, and side bladder 56 is fabricated from urethane coated nylon twill material radio frequency welded to join and seal the fabric in the illustrated geometry.

Illustratively head chamber 46 includes four individual cushions 44 and upper torso chamber 48 includes four individual cushions 44 so that each chamber 46, 48 has an overall length of sixteen inches (40.64 cm). Lower torso chamber 50 includes seven individual cushions 44 and thus has an overall length of twenty-eight

10

15

20

25

30

inches (71.12 cm). Foot chamber 52 includes five individual cushions 44 and thus has an overall length of twenty inches (50.8 cm).

The manner of inflation of side bladders 56 is not illustrated but may be accomplished through manual inflation valves (not shown) or by having side bladders 56 in fluid communication with one of the chambers 46, 48, 50, 52. Side bladders 56 allow the width of mattress 12 to be adjusted to accommodate common intensive care unit ("ICU") and medical-surgical ("med-Surg") frames. Typical ICU and Med-Surg frames include patient support surfaces having a width of 32-35 inches (81.28-88.9 cm). Illustratively air mattress 12 has a length of approximately 80 inches (203.2 cm) and a width adjustable between thirty-two inches (81.28 cm)(with side bladders deflated) and thirty-five inches (88.9 cm)(with side bladders inflated).

As shown in Fig. 3, bottom layer 36 includes a plurality of foam segments 70 and air support segment 72. As with air mattress layer 12, bottom layer 36 is divided into four segments, a head zone 76, an upper torso zone 78, a lower torso zone 80, and a foot zone 82. Illustratively head zone 76, upper torso zone 78, and lower torso zone 80 each include a plurality of urethane foam segments 70 inserted into urethane coated nylon twill sleeves. The sleeves are joined at regular intervals. This joining may be accomplished in the manner disclosed in U.S. Patent Application Serial No. 09/281,888. Foot zone 82 includes air support segment 72 having a plurality of air bladders 88 and plenums 90 underlying foot chamber 52 of air mattress 12.

Each foam segment 70 of head, upper torso, and lower torso zones 76, 78, 80 is thirty-two inches (81.28 cm) in overall length and includes a mid-section 84 extending between two end caps 86. Each foam segment 70 is four inches (10.16 cm) wide by four inches (10.16 cm) tall. Head and upper torso zone 76, 78 illustratively include four foam segments 70 each and thus each zone 76, 78 has an overall length of sixteen inches (40.64 cm). The mid-sections 84 of the foam segments 70 in the head and upper torso zones 76, 78 are a High Resiliency ("HR") grade foam of 2.25-2.5 density, support factor 2.4 minimum, 17-21 ILD, CAL 117, antimicrobial foam. Lower torso zone 80 illustratively includes seven foam segments 70 and thus has an overall length of twenty-eight inches (71.12 cm). The mid-sections 84 of the foam

10

15

20

25

30

segments 70 in the lower torso zone 80 are a HR grade foam of 2.25-2.5 density, support factor 2.5 minimum, 31-34 ILD, CAL 117, antimicrobial foam.

End caps 86 of all of foam segments 70 of zones 76, 78, 80 combine to form side rails on lower support 36 and are thus referred to as side rail foam. These side rails facilitate patient ingress to and egress from surface 10. In addition, end caps 86 and mid-sections 84 combine to create a cradle zone to facilitate adequate centering of patient to assist in keeping patient from sliding into the side rail and reducing the need for the caregivers to frequently reposition the patient. End caps 86 are bonded to mid-sections 70 with acetone heptane and resin base spray adhesive. Each end cap 86 is two inches (5.08 cm.) in overall length, four inches (10.16 cm) wide, and four inches (10.16 cm) tall to conform to the mid-section 70 to which it is attached. End caps 86 are made of conventional foam grade such as Foam Grade H45XF, 1.8-1.9 PCF, 53-60 ILD, support factor 2.0, Cal 117, antimicrobial foam.

Illustratively foot zone 82 includes air support segment 72 having five air bladders 88 extending between and fluidly coupled to two spaced apart plenums 90. Bladders 88 and plenums 90 are four inches (10.16 cm) in diameter. Thus foot zone 82 has an overall length of twenty inches (50.8 cm). Bladders 88 and plenums 90 are made of urethane coated nylon twill material, IAW material specification 100-001-0032. Bladders and plenums 90 are in fluid communication with the two plenums 54 that supply air to the foot chamber 52 of air mattress 12.

Force optimization surface 10 provides for sensing multiple interface pressures or forces exerted by the modifiable support surface 9 on a patient 16 atop sensor layer 14. Those skilled in the art will recognize that interface pressure measured in a defined area is the integral over the area of all of the forces exerted normal to the area. Therefore, the term force or interface force will be used to refer to the interface force or interface pressure unless otherwise stated to avoid confusion between pressure in an air bladder and the interface pressure. Support surface11 is coupled to a controller 18 configured with software for regulating air pressure within each chamber 46, 48, 50, 52 of mattress 12 based on measured interface force values exerted by the chambers 46, 48, 50, 52 on the patient 16. Various interface sensors 15 are known which detect the interface pressure and the interface force. In the illustrated embodiment of the invention, zones of the modifiable support surface 9 are

10

15

20

25

30

modified in response to the maximum force exerted within the zone using resistive force sensors located on each zone. A multiplicity of sensors detecting interface pressure can be used to detect this maximum force exerted within the zone, however in the illustrated embodiment an interface force sensor is described. To avoid confusion, the term interface sensor will be used to refer to both a multiplicity of interface pressure sensors or an interface force sensor.

Force optimization surface 10 with its controller 18 uses multiple interface sensor readings to decide how to modify pressure within a given chamber or chambers within mattress 12 to optimally reduce the interface force. The nature of the optimization can vary as desired, such as controlling air pressures to achieve a minimum average value for all interface sensor signal values, to maintain all interface sensor values below a threshold, or to achieve certain force profiles over various surface areas, etc.

Illustratively sensor layer 14 includes a peripheral downwardly extending sidewall 92 and a surface 94 extending between and combining with sidewall 92 to form a modifiable support surface-receiving cavity much like a fitted sheet, as shown for, example, in Figs. 3 and 4. Nevertheless, it is within the teaching of this disclosure for sensor layer 14 to include a mat disposed between air mattress 12 and top cover 42. Incorporated within surface 94 is a plurality of sensing zones which in the illustrated embodiment include head zone 96, upper torso zone 98, lower torso zone 100, and foot zone 102. In the illustrated embodiment, each sensing zone includes a peripherally extending non-sensing border 104 having a width 106 of one inch (2.54 cm), an outer covering 108, and an interface sensor 15. Illustratively, interface sensor 15 includes a top conductive layer 110 and a bottom conductive layer 112 separated by a semiconductor material 114, a first wire 116 coupled at one end to top conductive layer 110 and at the other end to controller 18, and a second wire 118 coupled at one end to bottom conductive layer 112 and at the other end to controller 18, as shown for, example, in Figs. 3, 4 and 5. Illustratively outer covering 108 is 0.002 in (.051 mm) thick aromatic polyether polyurethane film available from Deerfield Urethane (Route S-10 Box 185, South Deerfield, Massachusetts 01373) PT9200U or equivalent. Each conductive layer 110, 112 is illustratively Monsanto Flextron TM nickel coated copper rip stop nylon fabric. Semiconductor material 114 is

10

15

20

25

30

a piezo-resistive sheet available from Verg, Inc, Winnipeg, Canada. Illustrated interface sensor 15 acts to sense the maximum force exerted anywhere within the zone.

In the illustrated embodiment of sensor layer 14, head zone 96 is sixteen inches (40.64 cm) long and thirty-two inches (81.28 cm) wide and is positioned to lie adjacent to head chamber 46 of air mattress 12. Upper torso zone 98 is sixteen inches (40.64 cm) long and thirty-two inches (81.28 cm) wide and is positioned to lie adjacent to upper torso chamber 48 of air mattress 12. Lower torso zone 100 is twenty-eight inches (71.12 cm) long and thirty-two inches (81.28 cm) wide and is positioned to lie adjacent to lower torso chamber 50 of air mattress 12. Foot zone 102 is twenty inches (50.8 cm) long and thirty-two inches (81.28 cm) wide and is positioned to lie adjacent to foot chamber 52 of air mattress 12.

Alternative integrated interface sensing material in sensor layer 14 can be any material that provides multiple interface sensors 15 such as a resistive or capacitive film providing a grid or matrix of interface sensors. These interface pressure mapping technologies are well known to those of skill in the art, and provide for sensing and mapping interface pressures against the entire body contact area of patient 16. Illustrative interface pressure sensing and mapping devices include capacitive devices such as the X-SENSORTM pad available from the X-sensor company in Calgary, Canada or the EMEDTM system from Novel GmbH in Munich, Germany, resistive force sensing devices such as those available from Vista Med in Winnipeg, Canada or Tekscan in Boston, Massachusetts, or other sensor types such as pneumatic pressure sensors, etc. It will be understood that in order to determine the maximum force exerted within a zone, like the illustrated interface sensor does, a multiplicity of capacitive or pneumatic sensors would be required within each specific zone.

It will be understood that in the illustrated embodiment, lower support layer 42, air mattress 12, and sensor layer 14 are all divided into the same number and size of segments, chambers, or zones. Each segment, chamber, or zone corresponds and is associated with the chamber, segment, or zone underlying or overlying it. Thus, hereinafter the terms zones of modifiable support surface or zones of support surface assembly are occasionally used.

Referring again to Fig. 3 and 4, fire barrier 38 is designed to receive and substantially totally encompass lower foam/air layer 36 and upper air mattress

10

15

20

25

30

support layer 12. Fire barrier 38 is illustratively formed of stretchable 1 x 1 rib knit that is constructed of fiberglass and modacrylic fabric or equivalent IAW raw material specification 240-02-0019. Anti-shear lining 40 is formed to have a downwardly opening cavity to receive the fire barrier 38 lower support layer 36 and air mattress layer support 12 assembly in the manner of a fitted sheet. Anti-sheer lining 40 is constructed of a low coefficient of friction nylon, polyester twill, or an equivalent. Anti-sheer lining 40 is installed over the fire barrier 38 and air mattress 12 and under the top cover 42 to reduce sheer force to the patient.

Illustratively, top cover 42 and bottom cover 34 each include one half of a peripherally extending zipper 35. The half of the zipper 35 coupled to top cover 42 is sewn to urethane strips for sealing to the host material of top cover 42. Illustratively the host material of top cover 42 is a polyurethane coated, bi-directional stretch nylon substrate material. The half of the zipper 35 coupled to bottom cover 34 is sewn directly to the host material of bottom cover 34. The host material of bottom cover is illustratively a monomeric vinyl laminate fabric. The zipper starts and ends on the center line of the patient foot end 29. Anti shear lining 40, fire barrier 38, upper and lower support layers 12, 36 are received between top and bottom covers and enclosed therein by joining halves of zipper 35 to form support surface structure 11.

Controller 18 includes a smart board 19, a power supply 21, an air supply 23, a control I/O panel 25, and a pneumatic system 27. The illustrated power supply 21 is one of a 220 volt 50 Hz input, 24 volt DC, 110 volt AC output power supply or a 110 volt 50 Hz input, 24 volt DC, 110 volt AC output power supply coupled to power cord 17. Air supply 23 includes an air pump 31 such as a Thomas .35 cfm 24 VDC air pump and a blower 33 such as Amatec centrifugal blower each of which are mounted in controller 18, electrically connected to power supply 21 and fluidly coupled to pneumatic system 27. Blower 33 is a high volume low pressure blower used for rapid inflation of the air mattress 12 to bring the mattress to initial set pressures and to bring all zones of the mattress to maximum pressure during a max inflate mode 134. Pump 31 is a high pressure low volume pump used to increase pressures in chambers of air mattress 12.

Illustratively, control I/O panel 25 includes an alarm silence button 37, an alarm silence LED 39, a max inflate button 41, a max inflate LED 43, a zone 1 LED

10

15

20

25

30

45 which blinks when selected, a zone 2 LED 47 which blinks when selected, a zone 3 LED 49 which blinks when selected, a zone 4 LED 51 which blinks when selected, and a call for service LED 53. Illustratively, panel 25 is a membrane keypad adhesively secured to controller 18 and is connected to control electronics (not shown) on smart board 19 through a ribbon cable and PCB connector (not shown). Control panel 25 will provide operator feed back via the use of LEDs 39, 43, 45, 47, 49, 51, 53 including alarms and sensor malfunctions.

To meet CPR requirements, a one step manual emergency dump valve 55 is incorporated in a known manner into support surface assembly 11. The purpose of valve 55 is to dump air in the head, upper torso, and lower torso chambers 46, 48, 50 in fifteen seconds. Once CPR is completed, dump valve 55 is reset.

Pneumatic system 27 includes four stepper motor controlled zone selector needle valves (not shown), five pressure transducers 7 (shown diagrammatically in Fig. 2 only), a stepper motor controlled vent needle valve (not shown). Pneumatic system 27 is coupled to smart board 19 which includes a processor and firmware (not shown). Pneumatic system 27 includes air supply lines 57 fluidly coupled to each chamber 46, 48, 50, 52. Each supply line 57 is also coupled to the air supply 23 through a designated zone valve (not shown). A pressure sensing line (not shown) is connected to each supply line 57 and to a pressure transducer 7 electrically coupled to smart board 19. A vent line 59 is coupled to each supply line 57 through vent valve (not shown) to vent chambers 46, 48, 50, 52 when appropriate.

Controller 18 provides for measuring sensed interface forces in real time and modifying the modifiable support surface 9, i.e., controlling chamber pressures in air mattress 12 in the illustrated embodiment, as required to reduce interface forces between a patient and support surface assembly 11. Controller 18 is illustratively coupled to a mattress control system 20 that regulates pressure within chambers of mattress 12. For an example of a system that determines an index using pressures for evaluating interface pressure performance of a support surface see application serial no. 08/752,796, entitled Method and Apparatus for Evaluating a Support Surface, which is hereby incorporated by reference.

Controller 18 can be provided within force optimization surface 10 or as a separate component coupled to force optimization surface 10 via an appropriate

10

15

20

25

communication interface, such as wires or a wireless communication link. In the illustrated embodiment top and bottom wires 116, 118 from each sensor zone are coupled into an eight wire bundle 120 forming a portion of lead/tubing assembly 13 extending between support surface assembly 11 and terminating in a 9-pin D subminiature connector with finger twist lock screws 122 coupled to controller 18. Controller 18 further provides for coupling force optimization surface 10 to other external systems (not shown) over various types of links, such as a peer-to-peer communication network.

Software in controller 18 is configured to scan or monitor interface forces from interface sensors 15 to maintain desired support characteristics, such as minimizing the force between the patient and each zone of support surface assembly 11, regardless of the body position or the bed position. Thus, for example, if patient 16 rolls over onto his or her side, or if support surface assembly 11 is coupled atop an articulated bed frame that assumes a non-flat orientation, controller 18 will adjust pressures in air mattress 12, i.e., modify modifiable support surface 9, automatically to minimize forces between each zone and the patient. These adjustments can be made at a predetermined periodic rate or can be event-driven as required. The rate at which adjustments are made can further be limited or filtered as desired.

The software or firmware loaded into controller 18 includes a start phase 130, a force management phase 132, a max inflate mode 134, and a service mode 136. In describing these phases the term "zone" will be used to refer to the sensing zone 96, 98, 100, 102 and the underlying associated chamber 46, 48, 50, 52 respectively. These zones are referred to as zone 1 (head zone 96 and head chamber 46), zone 2 (upper torso zone 98 and upper torso chamber 48), zone 3 (lower torso zone 100 and lower torso chamber 50) and zone 4 (foot zone 102 and foot chamber 53). "Pressure in a zone" refers to the air pressure in the chamber underlying and associated with the sensing zone. "Force on a zone" refers to the interface force or pressure sensed by interface sensor 15.

The algorithm for start phase 130 is shown, for example, in Fig. 6.

Start phase 130 includes the steps of turning the blower on 138, sensing the current pressure in zones 1, 2, 3, and 4 (P₁₋₄) 140, comparing the current pressure in each zone to a set pressure for each zone 141, blowing air into each zone so long as the pressure

10

15

20

25

in all chambers is not greater than the respective set pressure for the chamber 142, and turning off the blower when the pressure in all zones is greater than a set initial pressure (P_{set}) 144. Typically after turning the blower off 144, one or more of the following steps of going to the max inflate mode 136 if the max inflate flag exists 146, going to the service mode 138 if the service flag exists 148, and continuing to the force management phase 132 after completion 150 are included in start phase 130.

The software includes a force management phase 132 which operates after the start phase 130 to adjust the pressure within each of the chambers underlying the sensor zones to minimize the force exerted between the surface and the patient. As shown, for example, in Fig. 7, at a high level, force management phase 132 includes a first manner of modification of modifiable support surface 9 or pumping procedure 131 and a second manner of modification of modifiable support surface 9 or venting procedure 133. Illustratively, the pumping procedure 131 includes the steps of ensuring that the pressure in a zone (P#) does not exceed a maximum pressure established for the chamber underlying the zone (P#max) before performing any pumping operation 152, and incrementally pumping air into the zone so long as the current force (F_#) in the zone is lower than the force recorded prior to the last incremental pumping (Fold) 154. The venting procedure 133 includes the steps of insuring that the pressure in a zone does not fall below a minimum pressure established for the zone (P_{#min}) before performing any venting operation 156 and incrementally venting the zone when the current force in the zone (F_#) exceeds the force recorded prior to the last pumping step (F_{old}) 158. The venting procedure 133 is continued so long as the current force (F_#) in the zone is less than the force recorded prior to last incremental venting (F_{old}), and the venting procedure 133 ceases when the current force in the zone (F_#) exceeds the force recorded prior to the last venting step (F_{old}). When pumping procedure 131 terminates the force management phase 132 goes to venting procedure 133 and when the venting procedure 133 terminates force management phase 132 returns to pumping procedure 131.

It will be understood that with a plurality of zones overlying a plurality
of associated independently inflatable chambers that each zone and its associated
chamber could be simultaneously controlled with a dedicated pump, valves and
controller or with a single controller, valve manifold, pump, and control algorithm

WO 00/24353

5

10

15

20

25

30

-13-

PCT/US99/25311

which cycles through the zones. It will also be understood that if modifiable support surface 9 is not an inflatable surface but an otherwise modifiable surface, similar subroutines will be included in pumping and venting procedure 131, 133 to ensure that limits of the modifiable surface are not exceeded and to modify the surface in different manners to facilitate reduction in forces between the surface and the patient. At a very high level force management phase 132 performs a first modification to the support surface so long as it continues to reduce the force between the surface and the patient and then performs a second modification to the surface for so long as it continues to reduce the force between the surface and the patient. Typically after performing the second modification, force management phase returns to the first modification, however if the modifiable support surface 9 can be modified in more than two manners, a third or more modifications may be performed.

One algorithm for implementing force management phase 132 for multiple zones and a single vent valve and pump is shown in Fig. 8 and includes the pumping procedure 131 and venting procedure 133. Pumping procedure 131 includes the steps of turning on the pump 170, selecting the valve to the next zone which is not in a no pump mode 172, measuring the current pressure (P_{θ}) in the selected zone 174, comparing the current pressure (P_{θ}) in the selected zone to a predetermined max pressure for that zone $(P_{\theta max})$ 176. If the current pressure is less than the max pressure $(P_{\theta} < P_{\theta max})$ for the zone the step of reading the current force (F_{θ}) on the zone 178 is performed, however, if the current pressure is greater than the maximum pressure then the step of putting the zone into no pump mode by setting the no pump flag for the zone 180 is performed as part of a loop described later either returning to the zone selection step 172 of pumping procedure 131 or exiting to venting procedure 133.

As long as the current pressure does not exceed the maximum pressure for the zone, the step of comparing the current force to the last recorded force on the zone 182 is performed. If the current force on the zone is less than the last recorded force, the goal of minimizing forces is being achieved by what is currently being performed, i.e., pumping, so the steps of replacing the recorded force with the current force $(F_{\#old}=F_{\#})$ 184 and pumping the zone for a set period of time 186 are performed during a loop that returns to the select zone step 172 of pumping procedure 131.

10

15

20

25

30

If during the comparison step 182 it is determined that the current force is not lower than the previously recorded force ($F_{\#} \ge F_{\#old}$), then whatever is currently being performed, i.e., pumping, is not working to achieve the desired results for the selected zone. Therefore the zone is not pumped anymore and the step of setting a No Pump Flag (NPF#) to establish that the zone is in a "no-pump mode" 180 is performed as part of a possible pumping procedure exit loop. Anytime the No pump mode step 180 is performed for a zone, that zone cannot be selected anymore during the current pumping procedure as the zone will no longer be a zone without a no pump flag. To avoid a continuous loop, the step of determining whether all of the zones are in no pump mode 188 is performed. If all zones are not in the no pump mode then the select zone step 172 is performed. However if all zones are in the no pump mode, the pumping procedure 131 is exited and the venting procedure 133 is performed. During the exit from pumping procedure 131 to venting procedure 133 the steps of clearing each zone out of no pump mode by clearing the no pump flags 190 and turning off the pump 192 are performed.

Venting procedure 133 includes the steps of opening the vent valve 200, selecting the valve to the next zone which is not in a no vent mode 202, measuring the current pressure $(P_{\#})$ in the selected zone 204, comparing the current pressure $(P_{\#})$ in the selected zone to a predetermined min pressure for that zone $(P_{\# min})$ 206. If the current pressure is greater than the min pressure $(P_{\#}>P_{\# min})$ for the zone the step of reading the current force $(F_{\#})$ on the zone 208 is performed, however, if the current pressure is less than the minimum pressure then the step of putting the zone into no vent mode by setting the no vent flag for the zone 210 is performed as part of a loop described later either returning to the zone selection step 202 of venting procedure 133 or exiting to pumping procedure 131.

As long as the current pressure does not dip below the minimum pressure for the zone, the step of comparing the current force to the last recorded force on the zone 212 is performed. If the current force on the zone is less than the last recorded force, the goal of minimizing forces is being achieved by what is currently being performed, i.e., venting, so the steps of replacing the recorded force with the current force $(F_{\text{fold}}=F_{\text{fl}})$ 214 and venting the zone for a set period of time 216 are

10

15

20

25

30

performed during a loop that returns to the select zone step 202 of venting procedure 133.

If during the comparison step 212 it is determined that the current force is not lower than the previously recorded force ($F_{\#} \ge F_{\#old}$), then whatever is currently being performed, i.e., venting, is not achieving the desired results for the selected zone. Therefore the zone is not vented anymore and the step of setting a No Vent Flag (NVF_#) to establish that the zone is in a "no-vent mode" 210 is performed as part of a possible venting procedure exit loop. Anytime the no vent mode step 210 is performed for a zone, that zone cannot be selected anymore during the current venting procedure as the zone will no longer be a zone without a no vent flag. To avoid a continuous loop, the step of determining whether all of the zones are in no vent mode 218 is performed. If all zones are not in the no vent mode then the select zone step 202 is performed. However, if all zones are in the no vent mode, then the venting procedure 133 is exited and the pumping procedure 131 is performed. During the exit from venting procedure 133 to pumping procedure 131 the steps of clearing each zone out of no vent mode by clearing the no vent flags 220 and closing the vent valve 222 are performed.

The control algorithm also includes a max inflate mode 134, shown, for example, in Fig. 9. The max inflate mode 134 includes the steps of closing the vent valve 230, opening the valve for all of the zones 232, turning the pump on 234, turning the blower on 236, measuring the pressure in each zone 238, and averaging the pressures in all of the zones (P_{avg}) 240. Then the step of comparing the average pressure to the maximum pressure 242 is performed. If the average pressure is not less than the maximum pressure $(P_{avg} \ge P_{max})$, then the steps of closing all of the valves 244, turning off the pump and blower 246, and illuminating the max inflate LED 248 are performed. If the average pressure is less than the maximum pressure $(P_{avg} < P_{max})$ then max inflate mode returns to the measuring pressure step 238.

The control algorithm also includes a call for service mode. A maximum service time will be selected. If the maximum service time has elapsed, the return from any pressure transducer equals zero, or if pressure does not rise in any zone after max service time, or if force readings are open or short circuit for max service time, the call for service LED 53 is illuminated.

WO 00/24353 PCT/US99/25311

5

10

15

20

25

30

-16-

While the invention thus far has been described as including four chambers and four sensing zones positioned between the four chambers and a surface on which a patient is located with each zone being responsive to changes in interface pressure or force over an associated chamber, it is within the teaching of the invention to include more or less than four chambers and four zones. Those skilled in the art to which this invention relate will recognize that higher resolution and greater control can be achieved by increasing the number of independently inflatable chambers or modifiable zones and associated sensor zones. It should also be recognized that independently inflatable chambers or modifiable zones and associated sensor zones can assume any configuration, orientation, or arrangement to facilitate controlling interface forces between patient and a surface on which patient is situated. In other words, zones can extend along a separate the support surface along both a length dimension and a width dimension of the support surface.

Controller 18 is configured to monitor peak interface force on a zone between patient 16 and mattress 12 and can reduce that force by adjusting pressure in one or more chambers. Controller 18 includes memory for storing and recording data such as sensor values and adjustments made over time. The data recorded by controller 18 can be used to analyze system performance and make assessments regarding patient 16. Controller 18 is further configured to interface with a display and/or printer output device 22 to provide for either visual or hard copy output both for recorded data and for data as it is acquired in real time.

Force optimization surface 10 further can be configured with a weighing system to sense, monitor, record, display, and print patient 16's weight. When a large number of force sensors are used, by integrating measured force values, interface sensors 15 can be used to derive weight information. However in the illustrated embodiment separate weight sensors 24 (diagrammatically illustrated only) are provided, such as force sensors in a bottom layer (not shown) of surface 10. One such force sensor includes a single bladder (not shown) internally lined with conductive material to indicate bottoming out so that the pressure in the bladder will be proportional to the weight of the patient when bottoming out is not indicated. A separate reference chamber is provided to determine the weight differential. As with interface sensors 15, a grid of weight sensors 24 can capture patient weight without

adverse effect from either the orientation of force optimization surface 10 atop an articulated frame or the orientation of patient 16 atop surface 10. Although weight sensors 24 can provide an absolute weight value, controller 18 can be configured to determine accurate weight change values from weight sensors 24 even if a precise absolute weight is not easily obtained. Even without an accurate absolute weight of patient 16, a caregiver can derive meaningful information concerning patient 16 based on knowledge of weight changes over time. Controller 18 can further be configured to detect a bed exit by patient 16 based on information from weight sensors 24, and provide an alert to caregivers accordingly.

10

15

20

5

An embodiment of force optimization surface 10 also includes integrated diagnostic sensors such as heart rate, respiration, and temperature sensors 26, 28, 30. Interface sensors 15 are used to obtain this information by monitoring pressure changes in real-time and analyzing the data to derive the vital characteristics. Software filters detect the appropriate respiration or heart rate signals. Non-invasive sensor systems for obtaining these patient parameters as are known in the art can also illustratively be integrated into force optimization surface 10 by embedding them into sensor layer 14. Temperature can be obtained through temperature sensing transducers or fabrics as are also known in the art. For example, thermistors may be provided in the piezo resistive sensing layer discussed above. These technologies provide diagnostic capabilities in that controller 18 can monitor and display vital signs of patient 16 such as heart rate, respiration rate, and skin temperature. Useful information about a patient 16 is provided both by display of the current values of these parameters and by analysis of this information recorded by controller 18 over a period of time.

25

Controller 18 includes software to monitor these conditions and provide alerts 32 when vital signs go out of predefined bounds. Various levels of alerts 32 can be provided, ranging from informational alerts for relatively minor deviations to emergency alerts upon detection of life threatening conditions.

Controller 18 can be coupled to other systems to signal these alerts, such as a system at a nurse station, an automated paging system, etc.

30

Controller 18 uses information from sensors 15, 26, 28, 30 to derive other diagnostic information related to patient 16, such as an apnea condition based on

10

15

monitoring of respiration rate based on interface pressure sensors 15 or from respiration sensor 28. Vital sign information from sensors 15, 26, 28, 30 can also be correlated to other measurements such as patient core temperature, pulse oximetry, etc. Force optimization surface 10 can further be configured with a vibrating mechanism that is activated by controller 18 upon detection of an apnea condition, in order to vibrate patient 16 gently to induce recovery. An alarm can be indicated if the apnea condition persists beyond a predetermined amount of time.

Force optimization surface 10 can further be configured to measure interface shear forces or pressures between patient 16 and surface 10 which can also restrict blood flow to patient 16 and contribute to development of pressure ulcers. Interface pressure sensors 15 as discussed above provide measuring a normal force. By providing sensors 15 that also sense shear forces, or separate shear force sensors (not shown), controller 18 can be configured to adjust air pressures in chambers of mattress 12 based on both normal and shear forces if the anti-shear layer 40 is not incorporated in support surface assembly 11.

Although the invention has been described in detail with reference to certain illustrated embodiments, variations and modifications exist within the scope and spirit of the invention as described and defined in the following claims.

15

20

25

30

CLAIMS:

A method of minimizing a force between a modifiable support
 surface and a patient located thereon, the method comprising the steps of:
 establishing an initial recorded force between the patient and the support surface;

performing a first procedure including modifying the support surface in a first manner for a predetermined time increment, measuring the current force between the patient and the surface, comparing the current force to the recorded force, and replacing the recorded force with the current force,

repeating the first procedure so long as the current force is less than the recorded force,

then performing a second procedure including modifying the support surface in a second manner for a predetermined time increment, measuring the current force between the patient and the support surface, comparing the current force to the recorded force, and replacing the recorded force with the current force, and

repeating the second procedure so long as the current force is less than the recorded force.

- 2. The method of claim 1, and further comprising the step of again performing the first procedure after the step of repeating the second procedure.
- 3. The method of claim 2, wherein the establishing step further comprises the step of establishing a maximum limit which cannot be exceeded during the first procedure and wherein the repeating the first procedure step continues so long as the current force is less than the recorded force and the maximum limit is not exceeded.
- 4. The method of claim 1, wherein the modifiable surface includes an inflatable chamber having a pressure and wherein the modifying step of the first procedure includes supplying air to the chamber.
- 5. The method of claim 4, wherein the modifying step of the second procedure includes venting air from the chamber.

15

20

25

- 6. The method of claim 4, wherein the establishing step includes the step of establishing a maximum pressure above which the chamber is not permitted to remain and the first procedure includes the step of comparing the pressure in the chamber following each supplying air step with the maximum pressure and continuing the first procedure only so long as the current pressure is below the maximum pressure.
- 7. The method of claim 5, wherein the establishing step includes the step of establishing a minimum pressure below which the chamber is not permitted to remain and wherein the second procedure includes the step of comparing the 10 pressure in the chamber following each venting air step with the minimum pressure and continuing the second procedure only so long as the current pressure is above the minimum pressure.
 - 8. A method of controlling the pressure in an inflatable surface containing a plurality of independently inflatable chambers to minimize a force exerted by each inflatable chamber on a patient, the method comprising the steps of:

establishing a minimum pressure for each chamber below which the pressure of the chamber is not permitted to remain, a maximum pressure for each chamber above which the pressure of the chamber is not permitted to remain, an initial set pressure for each chamber between the minimum pressure and the maximum pressure, and an initial recorded force for each chamber,

inflating each chamber until the pressure in each chamber is at substantially for that chamber,

performing a supply procedure including the steps of selecting a chamber which is not in a no-pump mode, supplying air to the selected chamber in an increment, measuring the current force on the selected chamber, comparing the current force on the selected chamber to the recorded force for the selected chamber, placing the selected chamber in a no-pump mode if the current force is not less than the recorded force for the selected chamber, replacing the recorded force for the selected chamber with the current force for the selected chamber, repeating the selecting, 30 supplying, measuring, comparing, placing, and replacing steps of the supply procedure until all zones are not in a no-pump mode,

10

15

20

25

then performing a vent procedure including the steps of selecting a chamber which is not in a no-vent mode, venting air from the selected chamber in an increment, measuring the current force on the selected chamber, comparing the current force on the selected chamber to the recorded force for the selected chamber, placing the selected chamber in a no-pump mode if the current force is not less than the recorded force for the selected chamber, replacing the recorded force for the selected chamber with the current force for the selected chamber, repeating the selecting, supplying, measuring, comparing, placing, and replacing steps of the vent procedure until all zones are in a no-vent mode,

then repeating the supply procedure.

9. A force optimization apparatus for minimizing forces between a support surface and a patient, the apparatus comprising:

a patient support surface including a plurality of independently controllable pressure sections and a force sensing material located in an upper support surface layer; and

a controller configured to adjust pressure in the support surface pressure sections based on sensed interface force for each section.

- 10. The apparatus of claim 9, wherein the controller is configured to analyze interface forces on multiple sections of the patient support surface and control pressure within the sections to reduce the interface force for each section.
- 11. The apparatus of claim 10, the controller is configured to reduce interface forces for each section without regard to support surface orientation;
 - 12. The apparatus of claim 9, including an integrated weight sensor.
- 13. The apparatus of claim 12, wherein the integrated weight sensor includes and air bladder.
 - 14. The apparatus of claim 12, wherein the weight sensor can be an integrated pressure sensing material incorporated into an upper support surface layer.
- 15. The apparatus of claim 12, wherein the controller is configured to monitor, record, or display a patient's weight or changes in weight from a preset value based on weight sensor information provided from the weight sensor integrated into the patient support surface.

15

20

30

- 16. The apparatus of claim 9, wherein the controller is configured to monitor, record, or display a patient's vital signs such as heart rate, reparations, and skin temperature based on information from one or more sensors integrated into a support surface.
- 5 17. The apparatus of claim 9, wherein the controller is configured to monitor apnea conditions based on information from a sensor integrated into the patient support surface.
 - 18. The apparatus of claim 9, wherein the controller is configured to signal an alert based on vital sign information derived from a sensor integrated into the support surface.
 - The apparatus of claim 9, wherein the controller is configured to monitor information from a sensor integrated into the patient support surface and to vibrate the patient support upon detection of an apnea condition based on the monitored information.
 - 20. A support surface apparatus comprising:at least one air bladder for supporting a person;
 - a force sensor located on the at least one air bladder, the force sensor being configured to measure a force between the person and the at least one air bladder;
 - an air supply coupled to the at least one air bladder; and
 a controller coupled to the force sensor, the controller being configured
 to adjust air pressure within the at least one air bladder based on the force detected by
 the force sensor to minimize the force between the person and the at least one bladder.
- The apparatus of claim 20, wherein the controller is configured to increase the air pressure in the at least one air bladder during a time period in which the force detected by the force sensor is decreasing.
 - 22. The apparatus of claim 21, wherein the controller stops increasing the air pressure in the at least one air bladder when the force detected by the force sensor increases, the controller being configured to decrease the air pressure in the at least one air bladder for a time period in which the force detected by the force sensor is decreasing.

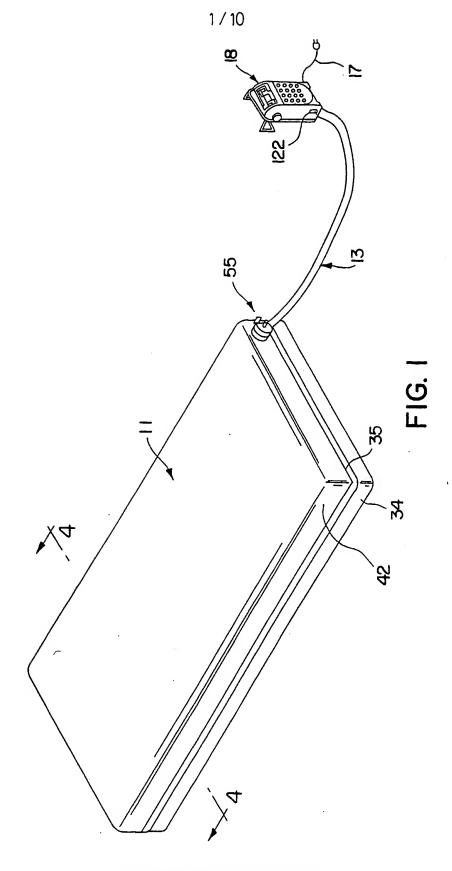
20

25

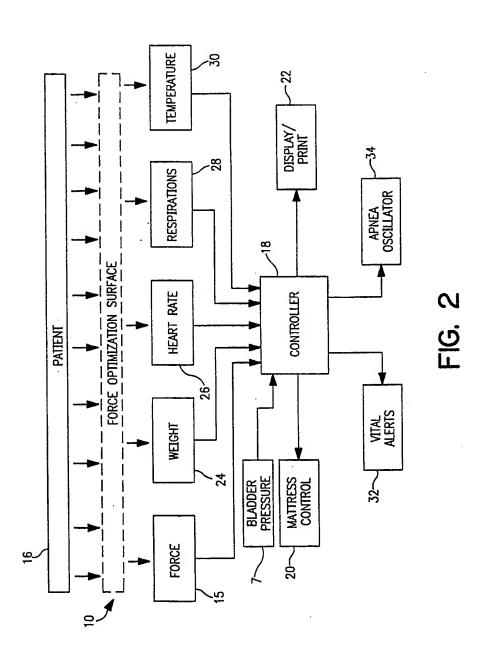
- 23. The apparatus of claim 22, wherein the controller is configured to maintain the air pressure within the at least one air bladder between a predetermined maximum pressure and a predetermined minimum pressure.
- 24. The apparatus of claim 20, wherein a plurality of separate air
 bladders are provided for supporting different portions of the person, and wherein a separate force sensor is located on each of the plurality of air bladders to measure the force between the person and each air bladder, the controller being configured to adjust air pressure within each of the plurality of air bladders based upon the forces detected by the force sensors to minimize the force between the person and each of the plurality of air bladders.
 - 25. The apparatus of claim 24, wherein the plurality of air bladders form separate support zones spaced along a length dimension of the support surface.
 - 26. The apparatus of claim 25, wherein the plurality of air bladders also form separate zones spaced along a width dimension of the support surface.
 - The apparatus of claim 20, wherein the force sensor is a resistive force sensor.
 - 28. The apparatus of claim 20, wherein the force sensor measures a maximum force on the at least one air bladder.
 - 29. The apparatus of claim 20, wherein the force sensor includes a plurality of capacitive force sensors located on the at least one air bladder.
 - 30. The apparatus of claim 20, wherein the force sensor includes a plurality of pneumatic force sensors located on the at least one air bladder.
 - 31. The apparatus of claim 20, wherein the force sensor includes thermistors which also measure a temperature on the sensor.
 - 32. The apparatus of claim 20, further comprising a weigh bladder located below the at least one air bladder, the weighing bladder being configured to measure a weight of the person on the at least one air bladder.
 - 33. A support surface apparatus comprising:at least one support member for supporting a person;
- a force sensor located on the at least one support member, the force sensor being configured to measure a force between the person and the at least one support member; and

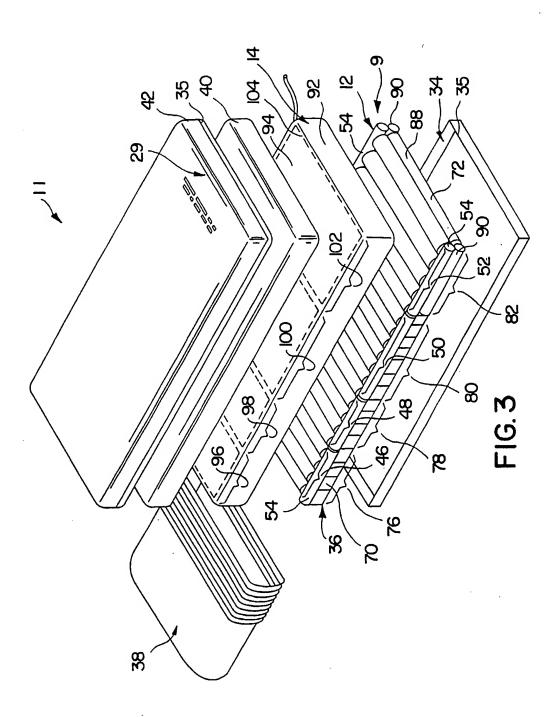
a mechanism configured to adjust a support characteristic of the at least one support member based upon the force detected by the force sensor to minimize the force between the person and the at least one support member.

PCT/US99/25311

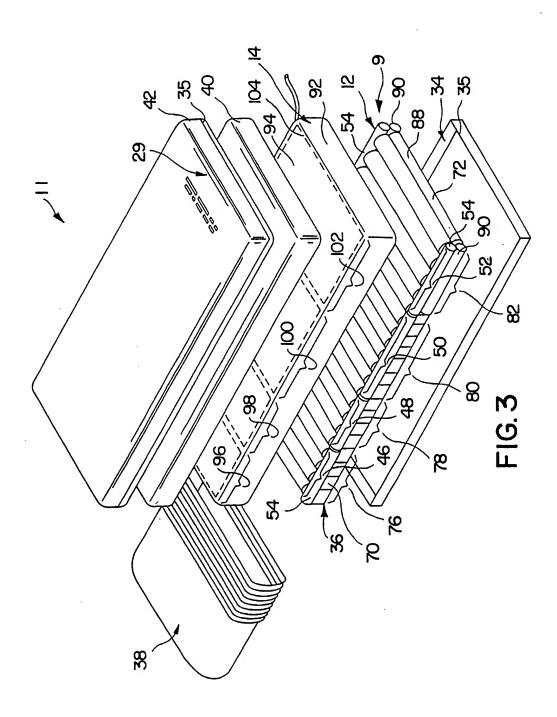


SUBSTITUTE SHEET (RULE 26)

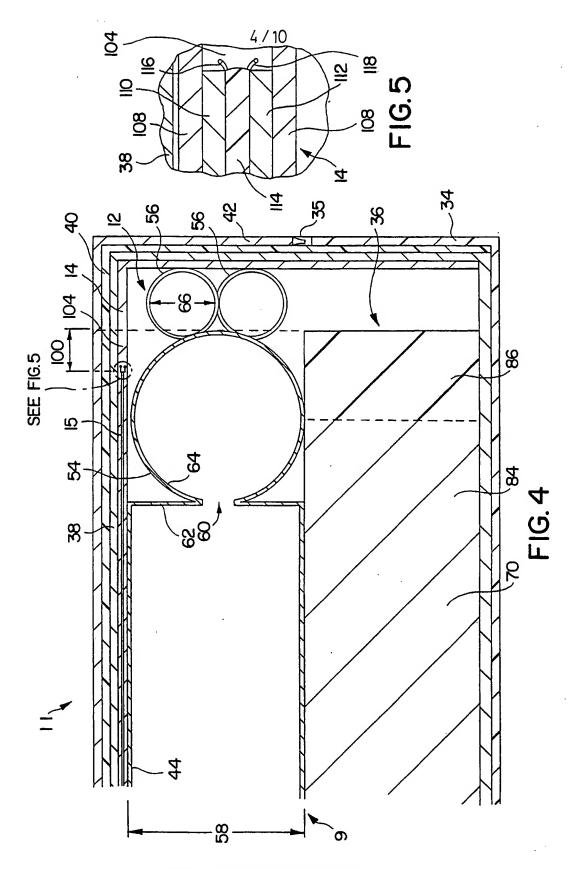




SUBSTITUTE SHEET (RULE 26)



SUBSTITUTE SHEET (RULE 26)



SUBSTITUTE SHEET (RULE 26)

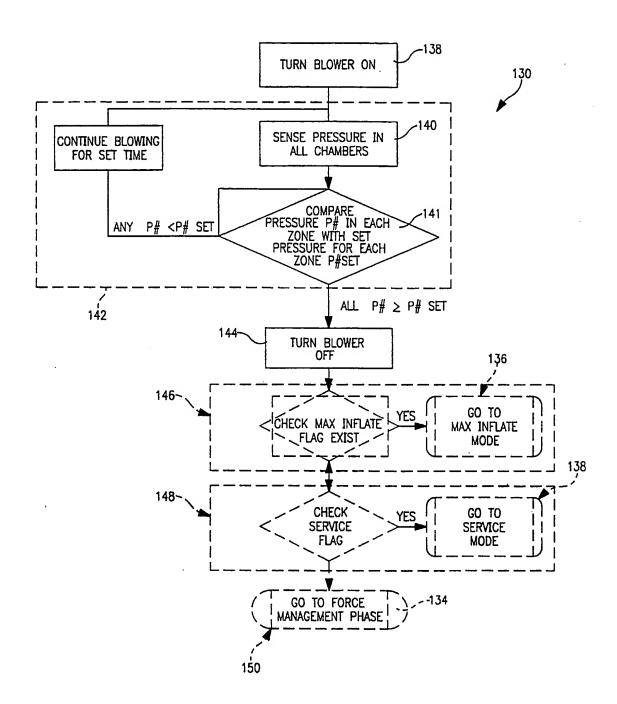


FIG. 6

SUBSTITUTE SHEET (RULE 26)

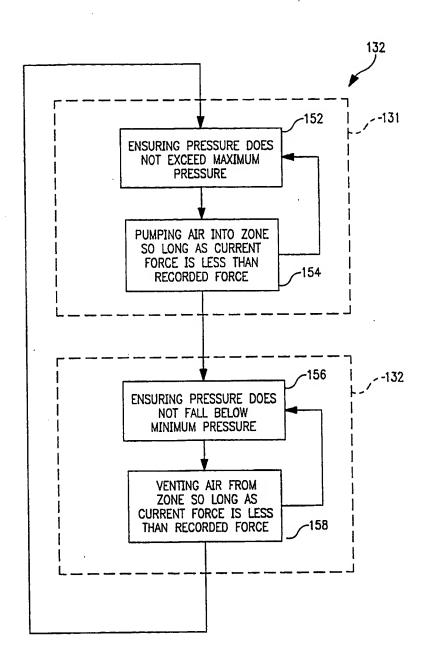


FIG. 7

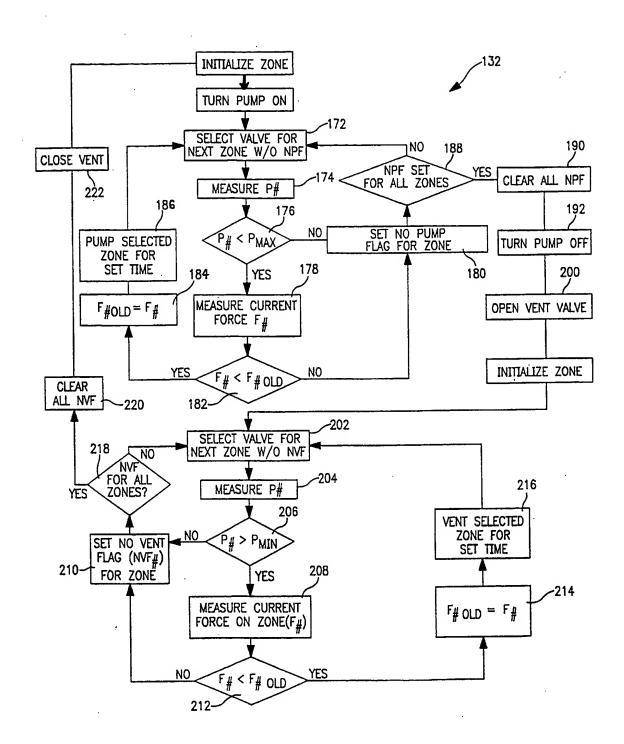


FIG. 8

SUBSTITUTE SHEET (RULE 26)

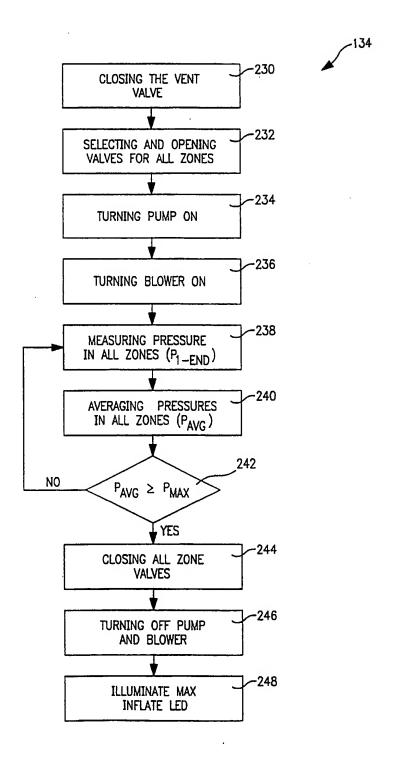


FIG. 9
SUBSTITUTE SHEET (RULE 26)

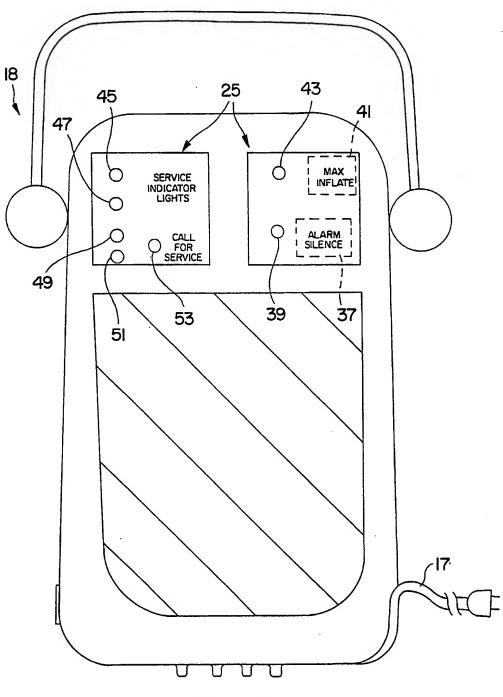


FIG. 10

10/10

